

### **III. Remarks**

#### **A. Amendments to the Specification**

The specification has been amended without prejudice to update the status of U.S. Serial No. 08/796,792, which was incorporated by reference. U.S. Serial No. 08/796,792 issued as U.S. Patent No. 6,087,163 after the filing of the present application. Applicants respectfully submit that no new matter has been added by virtue of this amendment.

#### **B. Status of the Claims**

Claims 1-8 and 11-20 are currently pending. Claims 9-10 and 21-36 were previously canceled. Claims 1, 11 and 17-20 have been amended without prejudice to include sequence reference numbers. Claim 16 has been amended without prejudice to correct a typographical error. Applicants respectfully submit that no new matter has been added by virtue of this amendment.

Prior to addressing the current rejections, Applicants wish to thank the Examiner for removing the rejection of claims 1-8 and 11-20 under 35 U.S.C. § 112, second paragraph, for indefiniteness for specific properties and number/identity of conservatively substitutions residues in light of Applicants' July 9, 2007 Amendments.

#### **C. Claim Rejections Under 35 U.S.C. § 112, first paragraph**

In the Final Office Action, claims 17-20 were rejected under 35 U.S.C. § 12, first paragraph, for scope of enablement for diagnostic methods utilizing polypeptides. Specifically, the Examiner referred to the "reasons of record", *i.e.*, the original rejection of May 4, 2005, alleging that "the specification contains no working examples of the claimed methods of detecting *M. tuberculosis* infected hosts utilizing the listed polypeptides or any other compositions."

This rejection is respectfully traversed. Applicants submit that the present specification has working examples of serologic immunoassays used to detect immune response to polypeptides of *M. tuberculosis* via the incorporation of U.S. Serial No. 08/796,792, now U.S. Patent No. 6,087,163 (attached herewith as Exhibit A), which was

incorporated by reference at page 13, lines 12-15 of the present specification. The Examiner is respectfully reminded that “[t]he information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed.” MPEP 8<sup>th</sup> Ed. 5<sup>th</sup> Rev. § 2163.07(b). Specifically, Applicants direct the Examiner’s attention to the ‘163 patent at col. 10, lines 13- col. 14, lines 20 , which exemplifies assays performed using polypeptide combinations for detection of TB specific antibodies. Additionally, the ‘163 patent at col. 7, line 1- col. 8, line 46 also describes in detail various routes of administration of polypeptides to a patient.

Accordingly, Applicants submit that the teachings of the present application, inclusive of the teachings of the ‘163 patent, enable one of skill in the art to make and use the invention in accordance with the present claims.

The Examiner further stated that “the specification contains insufficient guidance and no working examples to determine if any ‘segment’ of the claimed polypeptides actually has ‘specific antigenic properties; necessary for the diagnosis of *M. tuberculosis* infection” and that “Applicants argument that it would be routine to determine such specificity is merely an invitation to experiment without a reasonable expectation of success...”.

The Examiner is respectfully reminded that “[t]he test for enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue.” MPEP § 2164.01 citing *In re Angstadt*, 537 F.2d 498, 504 (CCPA 1976). In the instant case, Applicants respectfully submit that, in view of the limited number of polypeptide sequences claimed, the ample guidance provided by the present specification, e.g., via the ‘163 patent, and the knowledge of one of skill in the art, one would be able to determine segments of the claimed polypeptides which retain immunogenic properties, and any experimentation required would not be undue .

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be removed.

**D. Claim Rejections Under 35 U.S.C. § 112, second paragraph**

In the Final Office Action, the Examiner rejected claims 1-8 and 11-20 under 35 U.S.C. § 112, second paragraph because “the sequences are not claimed by any SEQ ID Number” and recommended “that the claimed sequences [be] identified by sequence identifiers, i.e., SEQ ID NO.”

In response, the claims have been amended without prejudice to include the appropriate sequence identifiers.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph be removed.

**IV. Conclusion**

In view of the amendments made and arguments presented, it is believed that all claims are in condition for allowance. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is invited to telephone the undersigned at (973)597-6162. The undersigned also may be contacted via e-mail at [epietrowski@lowenstein.com](mailto:epietrowski@lowenstein.com). All correspondence should be directed to our address listed below.

**AUTHORIZATION**

The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment, to Deposit Account No. 50-1358.

Respectfully submitted,  
Lowenstein Sandler PC

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